

We Claim:

- 1 1. A process for the preparation of crystalline Form II of orlistat, the process  
2 comprising:  
3 preparing a solution of orlistat in one or more ethers; and  
4 isolating the orlistat in the crystalline Form II from the solution thereof by the  
5 removal of the ether.
- 1 2. The process of claim 1, wherein the ether comprises one or more of diethyl ether,  
2 diisopropyl ether, tert.-butyl-methyl ether, and tetrahydrofuran.
- 1 3. The process of claim 2, wherein the ether is diisopropyl ether.
- 1 4. The process of claim 1, wherein removing the ether comprises one or more of  
2 distillation, distillation under vacuum, evaporation, filtration, filtration under  
3 vacuum, decantation and centrifugation.
- 1 5. The process of claim 1, wherein the solution of orlistat is obtained directly from a  
2 reaction mixture in which orlistat is formed.
- 1 6. The process according to claim 1, further comprising additional drying of the  
2 product obtained.
- 1 7. The process of claim 1, further comprising forming the product obtained into a  
2 finished dosage form.
- 1 8. The process of claim 1, wherein the orlistat Form II has the X-ray diffraction  
2 pattern of Figure 4.
- 1 9. The process of claim 1, wherein the orlistat Form II has the infrared spectrum of  
2 Figure 5.
- 1 10. The process of claim 1, wherein the orlistat Form II has the differential calorimetry  
2 plot of Figure 6.
- 1 11. A pharmaceutical composition comprising a therapeutically effective amount of  
2 Form II orlistat obtained by the process of claim 1; and one or more  
3 pharmaceutically acceptable carriers, excipients or diluents.

- 1 12. A method of treating or preventing obesity and hyperlaemia in a warm-blooded  
2 animal comprising administering a pharmaceutical composition that includes a  
3 crystalline Form II of orlistat obtained by the process of claim 1.
- 1 13. A process for the preparation of crystalline Form I of orlistat, the process  
2 comprising:  
3 obtaining a melt of orlistat; and  
4 drying the melt to get the Form I of orlistat.
- 1 14. The process of claim 13, wherein the melt is obtained by heating the orlistat.
- 1 15. The process of claim 14, wherein the heating is performed at a temperature from  
2 about 25°C to about 80°C.
- 1 16. The process of claim 15, wherein the heating temperature is from about 40°C to  
2 about 50°C.
- 1 17. The process of claim 13, wherein the drying is performed under reduced pressure.
- 1 18. The process of claim 13 further comprising cooling before drying the melt.
- 1 19. The process of claim 13 further comprising forming the product obtained into  
2 a finished dosage form.
- 1 20. The process of claim 13, wherein the orlistat Form I has the X-ray diffraction  
2 pattern of Figure 1.
- 1 21. The process of claim 13, wherein the orlistat Form I has the infrared spectrum of  
2 Figure 2.
- 1 22. The process of claim 13, wherein the orlistat Form I has the differential  
2 calorimetry plot of Figure 3.
- 1 23. A pharmaceutical composition comprising a therapeutically effective amount of  
2 Form I orlistat obtained by the process of claim 13; and one or more  
3 pharmaceutically acceptable carriers, excipients or diluents.
- 1 24. A method of treating or preventing obesity and hyperlaemia in a warm-blooded  
2 animal comprising administering a pharmaceutical composition that includes a  
3 crystalline Form I of orlistat obtained by the process of claim 13.